ISRCTN12376468 https://doi.org/10.1186/ISRCTN12376468

# Radiotherapy after Oesophageal Cancer Stenting (ROCS) study

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|---|---|---|
| **Submission date**<br>04/07/2012 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>10/07/2012 | **Overall study status**<br>Completed | |
| **Last Edited**<br>28/02/2023 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-radiotherapy-oesophageal-cancer-difficulty-swallowing-rocs

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number
NCT01915693

### Secondary identifying numbers
HTA 10/50/49, WCTU030

# Study information

### Scientific Title
Palliative radiotherapy in addition to self-expanding metal stent for improving dysphagia and survival in advanced oesophageal cancer: Radiotherapy after Oesophageal Cancer Stenting (ROCS) study

### Acronym
ROCS

### Study objectives
Radiotherapy in addition to self-expanding metal stent (SEMS) placement improves patient-reported dysphagia and increases time to progression in a patient population unable to undergo surgery.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/105049
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/81666/PRO-10-50-49.pdf

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Two-arm open randomised phase III trial with a 1:1 randomisation ratio. A qualitative component in a sub-set of patients.

### Primary study design
Interventional

### Secondary study design

Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Oesophageal cancer requiring stent for relief of dysphagia

## Interventions
Arm A: Self-expanding metal stents (SEMS) (Control Arm)
SEMS insertion will be undertaken in accordance with standard local protocols. Covered or partially covered metal stents will be used and the length type and mode of stent placement will be selected by the clinician. Insertion will occur within two weeks of randomisation.

Arm B: SEMS plus external beam radiotherapy (Intervention Arm)
External beam radiotherapy (EBRT) is routinely available at regional cancer centres across the UK. For palliation of dysphagia in oesophageal cancer, a radiotherapy course delivering a tumour absorbed dose of 20Gy in 5 fractions or 30Gy in 10 fractions within 4 weeks of SEMS insertion.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
Assess the impact of radiotherapy in addition to self-expanding metal stent (SEMS) placement on time to progression of patient-reported dysphagia in a patient population unable to undergo surgery.

## Secondary outcome measures
1. Assess the impact of combination treatment on core components of health related quality of life
2. Assess the impact of radiotherapy in addition to SEMS placement on overall survival
3. Measure morbidity associated with the interventions
4. Measure re-intervention rates
5. Assess the cost of the addition of radiotherapy to SEMS placement

## Overall study start date
01/10/2012

## Completion date
30/11/2018

# Eligibility

### Key inclusion criteria
1. Histological confirmation of oesophageal carcinoma excluding small cell histology
2. Not suitable for radical treatment (oesophagectomy or radical chemoradiotherapy) either because of patient choice or medical reasons
3. Dysphagia clinically assessed as needing stent as primary treatment of the dysphagia
4. Age 16 years or over
5. Discussion and treatment decision for SEMS placement made by an Upper GI multi-disciplinary team
6. Clinician assessment of ability to attend for radiotherapy
7. Expected survival of at least 12 weeks
8. Written informed consent

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
496

### Total final enrolment
220

### Key exclusion criteria
1. Histology of small cell carcinoma type
2. Tumour length of greater than 12 cm
3. Tumour growth within 2 cm of the upper oesophageal sphincter
4. Endoscopic treatment of the tumour, other than dilatation, planned in the peri-stent period
5. Presence of a tracheo-oesophageal fistula
6. Presence of a pacemaker
7. Previous radiotherapy to the area of the proposed radiotherapy field
8. Planned endoscopic treatment of the tumour (e.g. laser) in the immediate peri-stenting period
9. Pregnancy

### Date of first enrolment
01/10/2012

### Date of final enrolment
31/08/2018

# Locations

### Countries of recruitment
Scotland

United Kingdom

**Study participating centre**
**Ward 32**
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# Sponsor information

**Organisation**
Velindre NHS Trust (UK)

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**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/05ntqkc30

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Health Technology Assessment Programme - HTA (UK), 10/50/49

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date
30/03/2021

## Individual participant data (IPD) sharing plan
Not provided at time of registration

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 22/10/2014 | | Yes | No |
| Results article | results | 01/04/2021 | 22/02/2021 | Yes | No |
| Results article | | 01/05/2021 | 28/05/2021 | Yes | No |
| Plain English results | | | 28/02/2023 | No | Yes |